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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,981	03/03/2000	Julie A. Bearcroft	P01952US0	5566

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/517,981	Applicant(s) BEARCROFT ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,64-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 64-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21, 22 are also rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

These claims are written to describe types of bone deficiencies and diseases, but do not recite any treatment or specific steps of how to treat these claimed bone problems. Additionally, there is an inconsistency in the preamble language of these dependent claims that depend from claim 1 (a particle). Applicant cannot claim a bone deficiency or disease, since 35 U.S.C. 101 states an applicant is entitled to a patent for new processes or compositions. However, claims 21 and 22 claim existing bone deficiencies and diseases, which applicant did not invent.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19, 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is an inconsistency between the language of the preambles reciting "the array" and "the particles" and the preamble of the independent claim (1), reciting "A shaped particle". Therefore, the scope of the claim is unclear as to what is intended to be claimed, the subcombination (a particle) or the combination of particles forming an array. The language of the claim must be consistent with the intent and clearly if claims 17-19, 23-25 are to further define claim 1, then they should define a particle not a grouping of particles.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10, 14, 17, 20, 21-23, 26, 64,65 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (5258028). Ersek et al. disclose (Fig. 5) a shaped particle with a center portion and at least six tapered extremities projecting from the center portion. Ersek discloses the array of particles have an adequate porosity to allow

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ingrowth, col. 5, lines 49-56. The particles are used for bone tissue repair, col. 9, lines 54-60. The materials forming the particles can include ceramics and polymers, col. 6, lines 45-57 and the diameter of the particle can be about 3mm, col. 6, lines 31-40.

It is inherent that the implantable material can be used as a filler for a bone malignancy that has bone loss.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 9, 10, 17, 20-23, 26, 64, 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (WO 94/08912). Sheppard et al. disclose the use of ceramics and polymers for the aggregate or array of particles, page 19, lines 26-28. Figs. 5 and 6 show an array of particles with tapered extremities extending from a center portion. Fig. 2 shows the particle with six extremities. Sheppard also discloses that ceramics can be used in bone replacement and periodontal disease requiring tooth implants, page 32, lines 20, 27. The particles can include ceramics and glasses of which can be interpreted broadly to encompass a substance that enables bone ingrowth, page 19, lines 26-29. However, Sheppard does not disclose a circular transverse configuration. It would have been an obvious matter of design choice to a person of ordinary skill in the art to use a circular shaped cross section configuration because Applicant has not disclosed that this shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with

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four-sided cross-section because this configuration also permits interlocking with adjacent particle extremities as claimed. Therefore, it would have been an obvious matter of design choice to modify Sheppard to obtain the invention as specified in claim 1, 26.

Claims 5, 6, 9, 11-13, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028 in view of Chen et al. (6180606). Ersek is explained supra. However, Ersek does not disclose the claimed materials for the particles or composite materials. Chen et al. teach that compositions used in periodontal repair is formed of calcium compounds, col. 2, lines 13-25. Polymers such as polylactic acid can be used for the matrix and composites can also be formed of polymer/ceramic or glass combinations, col. 3, lines 40, 41, 47-50, 60-65. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the suggested materials and combinations as taught by Chen for the particles of Ersek in order to enhance the osteogenic potential of the composition being used.

Claims 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028 in view of Kondo et al. (JP 171546). Ersek is explained supra. However, Ersek does not disclose the particle diameter in the range of 6mm. Kondo et al. teach forming particles with protruberances or extremities on the surface having a diameter of 8mm, page 3, lines 9, 10. It would have been obvious to one of ordinary skill in the art to use the teaching of Kondo to use diameters "about" 6 to 8mm for the particle of Ersek in order to encourage greater tissue ingrowth.

Claims 7, 8, 18, 19, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028 in view of Kelly et al. (5676745). Ersek is explained supra. However, Ersek does not disclose the ceramic as gypsum and to use mixtures or to have a porosity between 40-80%. Kelly et al. teach that composites for bone implants or restoration (col. 1, lines 51-59) can be mixed with different materials, col. 2, lines 18-23, 58-62. Kelly also teaches that gypsum can be used for the particles of the composition, col. 4, lines 19-20. The porosity is about 40%, col. 3, lines 3,4. It would have been obvious to one of ordinary skill in the art to use the teachings of Kelly for providing mixtures of materials and having a porosity of about 40% for the particles of Ersek in order to facilitate bone ingrowth within the framework of the implant.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028. Ersek is explained supra. However, Ersek does not disclose a porosity between 60-80% for the array of particles. It would have been an obvious expedient to have the porosity between 60-80%, since applicant has not disclosed that an array having this specific range of porosity provides an advantage, solves any stated problem or is for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any porosity because bone ingrowth will occur in any pore size.

Response to Arguments

Applicant's arguments filed 6/11/02 have been fully considered but they are not persuasive. In response to Applicant's remarks regarding Sheppard, it is agreed that the reference does not disclose a circular cross-section. However, a change in shape is

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generally recognized to be within the level of ordinary skill in the art and since the Applicant does not disclose that the circular cross-section provides any advantage the claims are obvious over Sheppard. With respect to Ersek, references are to be considered in their entirety. Ersek discloses a particle as the claimed invention. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a description of the surface of the particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Note that the surface of the particle extremities in Fig. 5 of Ersek do not show irregularities.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino



Paul Prebilio

Primary Examiner

August 23, 2002

TC 3700, AU 3738